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In re Application of
Richardson et al.
Serial No.: 10/058,835
Filed: January 30, 2002
Attorney Docket No.: UMICH-11

Decision on Petition

This letter is in response to the Petition under 37 C.F.R. 1.181, filed on September 29, 2005, to request the supervisory authority of the Commissioner in a matter involving an *ex parte* restriction requirement. The delay in responding to this petition is regretted.

BACKGROUND

Review of the file history shows that the application was filed January 30, 2002 under 35 U.S.C. 111(a). The application as filed contained 31 claims. On June 2, 2004 the examiner mailed a restriction requirement dividing the claims into 12 groups. On June 21, 2004 applicants filed a response in which they elected Group I. Applicants traversed the restriction requirement, arguing that the 12 groups represent species of a single generic invention. Applicants also argued that the inventions are not "unrelated" as stated by the examiner. On August 12, 2004 the examiner mailed a first Office action on the merits, in which the restriction requirement was made final. The examiner reasoned that the groups as claimed were patentably distinct because different substances are administered. On February 10, 2005 applicants filed a response canceling the claims drawn to groups 11 and 12, and repeating their traverse of the restriction requirement with regard to the other 10 groups, on essentially the same grounds as presented in the instant petition. In a final rejection mailed on May 17, 2005 the examiner maintained the restriction requirement without further comment. On March 3, 2006 (after filing the petition) applicants filed a response canceling all the claims and adding a new set of claims with a somewhat narrower scope.

DISCUSSION

Applicants argue that the inventions as set forth by the examiner are not "unrelated." This is correct; the inventions are clearly related. Related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). When analyzed by this standard, it is clear that the examiner made more than one error in the restriction requirement. In the Office action of August 12, 2004, the examiner correctly argues that methods requiring administration of peptides, nucleic acids and "small molecules" are patentably distinct, i.e. not obvious variants, due to their differing design and modes of operation. However, group II is drawn to administration of a peptide while group I is drawn to administration of TNF-α, which is a peptide itself. Thus, groups I and II overlap in scope and are not patentably distinct. Moreover, while groups I-IV recite fat as the target tissue with different agents being administered, groups V-X each recite a different target tissue without regard for the type of agent being administered. Is the examiner's position that methods requiring administration of different agents are patentably distinct only if fat is the target tissue? There does not seem to be any basis for this position.

Applicants argue that election of species practice should have been applied. This argument is persuasive, though applicants ignore the fact that there are several variables in play: the target tissue, the agent to be administered, and the formulation of the controlled release carrier. A reasonable election of species would have required applicants to elect a single target tissue, a single agent to be administered and a single carrier formulation.

It is pointed out that the new claims submitted by applicants are limited to a single target tissue- fat, but still contain a confusing Markush group of overlapping species of agents to be administered and another Markush group of carrier formulations.

DECISION

Applicants' petition is **GRANTED** to the extent that the original restriction requirement is vacated. The examiner is instructed to either examine the claims in their entirety or to require election of species in accordance with the guidance in the MPEP (restriction being at the discretion of the examiner).

The application will be forwarded to the examiner to take appropriate action as a result of this petition.

Should there be any questions regarding this decision, please contact Special Program Examiner Marianne Seidel, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 703-872-9306.

George Elliott
Director, Technology Center 1600